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Date: August 9, 2006

To Examiner : Alstrum Acevedo, James Henry
Group 1616

From: Carolyn S. Elmore, Esq.
Registration No. 37,567

Fax Number: (571) 273-8300

Subject: Paper: Second Petition Under 37 CFR 1.181
Docket No.: 2685.2046 US3
Applicants: Richard P. Batycky, *et al.*
Serial No.: 10/607,571
Filing Date: June 26, 2003

Number of pages including this cover sheet 9

Please confirm receipt of facsimile: Yes XX No _____

Comments:

AF

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Elmore Patent Law Group, P.C., 209 Main Street, N. Chelmsford, MA 01863, USA. Tel: (978) 251-3509 / Fax: (978) 251-3973 www.elmorepatents.com

AUG 09 2006

2685.2046 US3

Expedited Procedure under 37 CFR 1.116Examining Group 1616

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Richard P. Batycky, Giovanni Caponetti, Mariko Childs, Elliot Ehrich,
Karen Fu, Jeffrey S. Hrkach, Wen-I. Li, Michael M. Lipp, Mei-Ling Pan and
Jason Summa

Application No: 10/607,571

Group No.: 1616

Filed: June 26, 2003

Examiner: Alstrum Acevedo, James Henry

Confirmation No.: 6287

Title: INHALABLE EPINEPHRINE

| | |
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| CERTIFICATE OF MAILING OR TRANSMISSION | |
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| <i>Hollie Wakefield</i> | <i>8-9-2006</i> |
| Signature | Date |
| HOLLIE WAKEFIELD | |
| Typed or printed name of person signing certificate | |

SECOND PETITION UNDER 37 CFR 1.181

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is the second petition filed under 37 CFR 1.181 in the above identified application. The first petition, timely filed on June 6, 2006 under 37 CFR 1.181. A copy of the first petition is attached together with the facsimile cover sheet and confirmation of facsimile transmission. Also enclosed is a confirmation executed by Ms. Hollie Wakefield that she did in fact execute the certificate on the June 6, 2006 Petition and fax the paper to the facsimile number identified on the facsimile cover sheet. The undersigned reviewed the status of the above identified patent application and discovered that the petition was not recorded in PAIR. As such, this paper is necessary. To ensure that this paper is forwarded to the correct individuals, it too is filed as a petition. Consideration of these petitions is respectfully requested.

Application No.: 10/607,571
Petition under Rule §1.181

Applicants hereby petition the Commissioner for Patents under 37 C.F.R. §1.181 to withdraw the finality of the office action mailed April 6, 2006 in the above-identified application.

In response to the first office action in the above-identified application dated September 9, 2005, Applicants amended the claims to incorporate a claim limitation of dependent claim 145 into independent claim 140. In response to Applicants' amendment and accompanying remarks, the Examiner withdrew all previous rejections and issued a final office action dated April 6, 2006, rejecting the claims under §§102 and 103 over new prior art cited not previously cited in the application. The Examiner also stated that Applicants' amendment necessitated the new ground of rejection citing MPEP §706.07(a).

In accordance with MPEP §706.07(a), "A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should *not* be made final if it includes a rejection, on prior art not of record, of *any claim amended to include limitations which should reasonably have been expected to be claimed*" [emphasis added]. In the present application, Applicants added the limitation of dependent claim 145 to independent claim 140 and canceled claim 145. Amended claim 140 is of *identical* scope to that of the previously presented claim 145 (now canceled). Clearly, an amendment to an independent claim that merely adds a dependent claim limitation present in a previously presented and examined claim set is *expected* particularly in view of the fact that the limitation was already specifically claimed in the previously presented and examined claim set. Clearly, such an amendment does not necessitate a new ground of rejection of *at least* amended claim 140. The finality of the rejection is improper under these circumstances. Applicants respectfully request that this petition be granted and that the finality of the Examiner's rejection in the Office Action be withdrawn.

As no decision on the first petition was received, an Amendment after Final Rejection was filed on July 20, 2006. The amendment was refused entry in the Advisory Action dated August 1, 2006. Applicants additionally petition the Director to direct the Examiner to enter the amendment. It is appreciated that in the event that the Finality of the Office action is removed, that the amendment submitted on July 20, 2006 will be entered. Nonetheless, in the event that the first petition is denied, it is respectfully requested that the amendment be entered.

The Amendment introduces into independent Claim 140 (directed to methods of administering particles containing epinephrine possessing specified physical characteristics) Claim 155 (limiting the method of administration to an inhalation to a single breath activated step),

Application No.: 10/607,571
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eliminating the need for Claims 151 and 154 of intermediate scope, and the dose of Claim 152. The Advisory Action recognizes that the amendment does not raise the issue of new matter or any other new issue. The reason for refusing to enter the amendment is that the amendments do not simplify or reduce the issues on appeal. This is simply not understood. How can an amendment that focuses the issues to a specified inhaler by a specified inhalation method not reduce the issues on appeal. Unless the amendment is entered, any appeal brief, examiner's answer and decision would need to independently consider the limitations of Claims 140, 151, 152, 154 and 155. Certainly, such an amendment is in compliance with 37 CFR 1.116.

No fee is believed to be due. Nonetheless, in the event that the USPTO determines that a fee is necessary, please charge the fees to Deposit Account No. 502807. Please charge any deficiency or credit any overpayment in the fees that may be due in this matter to Deposit Account No. 502807.

Respectfully submitted,

ELMORE PATENT LAW GROUP, PC

By 

Carolyn S. Elmore

Registration No. 37567

Telephone: (978) 251-3509

Facsimile: (978) 251-3973

N. Chelmsford, MA 01863

Dated: 8/9/6

AUG 09 2006

2685.2046 US3

Expedited Procedure under 37 CFR 1.116

Examining Group 1616

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Richard P. Batycky, Giovanni Caponetti, Mariko Childs, Elliot Ehrich,
Karen Fu, Jeffrey S. Hrkach, Wen-I. Li, Michael M. Lipp, Mei-Ling Pan and
Jason Summa

Application No: 10/607,571

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Examiner: Alstrum Acevedo, James Henry

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| <i>Hollie Wakefield</i> | <i>8-9-2006</i> |
| Signature | Date |
| HOLLIE WAKEFIELD | |
| Typed or printed name of person signing certificate | |

PERSONAL STATEMENT BY HOLLIE WAKEFIELD

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Hollie Wakefield, of Elmore Patent Law Group, PC hereby personally attest that, on June 6, 2006, I signed the certificate of mailing appearing on the enclosed Petition Under 37 CFR 1.181 and transmitted the document by facsimile to the number stated on the Facsimile Cover Sheet.
Respectfully submitted,

By *Hollie Wakefield*
Hollie Wakefield

Tel.: (978) 251-3509

Fax: (978) 251-3973

N. Chelmsford, Massachusetts 01863

Date: *8/9/2006*

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AUG 09 2006 2685.2046 US3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Richard P. Batycky, Giovanni Caponetti, Mariko Childs, Elliot Ehrich,
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Jason Summa

Application No: 10/607,571

Group No.: 1616

Filed: June 26, 2003

Examiner: Alstrum Acevedo, James Henry

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Title: INHALABLE EPINEPHRINE

Copy to Client

Date: 6/13/06

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| <i>Hollie Wakefield</i> | <i>6-6-2006</i> |
| Signature | Date |
| HOLLIE WAKEFIELD | |
| Typed or printed name of person signing certificate | |

PETITION UNDER 37 C.F.R. §1.181

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby petition the Commissioner for Patents under 37 C.F.R. §1.181 to withdraw the finality of the office action mailed April 6, 2006 in the above-identified application.

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Application No.: 10/607,571
Petition under Rule §1.181

In accordance with MPEP §706.07(a), "A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should *not* be made final if it includes a rejection, on prior art not of record, of any claim *amended to include limitations which should reasonably have been expected to be claimed*" [emphasis added]. In the present application, Applicants added the limitation of dependent claim 145 to independent claim 140 and canceled claim 145. Amended claim 140 is of identical scope to that of the previously presented claim 145 (now canceled). Clearly an amendment to an independent claim that merely adds a dependent claim limitation present in a previously presented and examined claim set is *expected* particularly in view of the fact that the limitation was already specifically claimed in the previously presented and examined claim set. Clearly such an amendment does not necessitate a new ground of rejection. The finality of the rejection is improper under these circumstances. Applicants respectfully request that this petition be granted and that the finality of the Examiner's rejection in the Office Action be withdrawn.

Please charge the fees to Deposit Account No. 502807 to cover the fees required for filing the indicated documents. Please charge any deficiency or credit any overpayment in the fees that may be due in this matter to Deposit Account No. 502807.

Respectfully submitted,

ELMORE PATENT LAW GROUP, PC

By 

Darlene A. Vanstone

Registration No. 35,729

Telephone: (978) 251-3509

Facsimile: (978) 251-3973

N. Chelmsford, MA 01863

Dated: *June 6, 2006*



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Date: June 6, 2006

To Examiner: James Henry Alstrum Acevedo
Group 1616

From: Darlene A. Vanstone
Registration No. 35,729

Fax Number: (571)273-8300

Subject: **Paper:** Petition Under 37 CFR 1.181

Docket No.: 2685.2046 US3

Applicants: Richard P. Batycky, *et al.*

Serial No.: 10/607,571

Filing Date: June 26, 2003

Number of pages including this cover sheet 3

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 *** ACTIVITY REPORT ***

| ST. TIME | CONNECTION TEL/ID | SENDER NAME | NO. | MODE | PGS. | RESULT |
|-------------|-------------------|-------------|------|--------------|------|----------|
| 06/01 11:18 | 011442075394299 | | 2633 | TRANSMIT ECM | 2 | OK 00'39 |
| 06/01 12:28 | 16177473970 | | 2634 | TRANSMIT G3 | 3 | OK 01'15 |
| 06/01 14:18 | 19782039223 | | 2635 | TRANSMIT ECM | 5 | OK 01'57 |
| 06/02 13:29 | 15712738300 | | 2636 | TRANSMIT ECM | 22 | OK 06'05 |
| 06/02 13:37 | 15712730140 | | 2637 | TRANSMIT ECM | 5 | OK 02'00 |
| 06/02 14:19 | ARIAD Finance | | 2638 | TRANSMIT ECM | 2 | OK 00'27 |
| | 16172252860 | | | | | |
| 06/05 11:49 | HYBRIDON, INC | | 2639 | TRANSMIT ECM | 2 | OK 00'27 |
| | 16176795560 | | | | | |
| 06/05 13:09 | 16179517050 | | 2640 | TRANSMIT ECM | 2 | OK 00'45 |
| 06/06 12:34 | 01181669106735 | | 2641 | TRANSMIT ECM | 3 | OK 00'35 |
| 06/06 12:37 | 011441732450113 | | 2642 | TRANSMIT ECM | 3 | OK 00'32 |
| 06/06 12:39 | 01181669106735 | | 2643 | TRANSMIT ECM | 3 | OK 00'38 |
| 06/06 12:43 | 17035675519 | | 2644 | TRANSMIT ECM | 3 | OK 00'47 |
| 06/06 12:45 | 16135639869 | | 2645 | TRANSMIT ECM | 1 | NG 00'48 |
| | | | | | 1 | |
| 06/06 12:47 | 16135639869 | | 2646 | TRANSMIT ECM | 3 | OK 02'07 |
| 06/06 12:50 | 01161392542770 | | 2647 | TRANSMIT ECM | 4 | OK 00'52 |
| 06/06 12:54 | 01161392542770 | | 2648 | TRANSMIT ECM | 8 | OK 01'23 |
| 06/06 12:58 | 01181669106735 | | 2649 | TRANSMIT ECM | 2 | OK 00'27 |
| 06/06 17:01 | 15712738300 | | 2650 | TRANSMIT | 0 | NG 00'38 |
| | | | | | 0 | |
| 06/06 17:07 | 15712718300 | | 2652 | TRANSMIT | 0 | NG 00'00 |
| | | | | | 0 | STOP |
| 06/06 17:09 | 15712738300 | | 2654 | TRANSMIT ECM | 3 | OK 00'54 |
| 06/07 17:22 | 011441732450113 | | 2655 | TRANSMIT ECM | 2 | OK 00'27 |
| 06/08 09:30 | 15712738300 | | 2656 | TRANSMIT ECM | 3 | OK 01'04 |
| 06/08 10:58 | 15712738300 | | 2657 | TRANSMIT ECM | 4 | OK 01'00 |
| 06/08 11:07 | 011442075394299 | | 2658 | TRANSMIT ECM | 43 | OK 16'42 |
| 06/08 11:29 | 0118227537315 | | 2659 | TRANSMIT ECM | 43 | OK 21'09 |
| 06/08 12:00 | 01161392542770 | | 2660 | TRANSMIT ECM | 43 | OK 07'38 |
| 06/08 12:15 | 17035675519 | | 2661 | TRANSMIT ECM | 44 | OK 07'48 |
| 06/08 12:29 | 16135639869 | | 2662 | TRANSMIT ECM | 43 | OK 46'51 |
| 06/08 13:17 | | | 5070 | AUTO RX ECM | 2 | OK 01'14 |
| 06/08 13:23 | 0117959249540 | | 2664 | TRANSMIT | 0 | NG 00'00 |
| | | | | | 0 | STOP |
| 06/08 13:24 | 01170959249543 | | 2665 | TRANSMIT | 0 | NG 00'00 |
| | | | | | 0 | STOP |
| 06/08 13:25 | 0117959249543 | | 2666 | TRANSMIT | 0 | NG 00'00 |
| | | | | | 0 | STOP |
| 06/08 13:30 | 01174952218885 | | 2667 | TRANSMIT G3 | 0 | NG 00'39 |
| | | | | | 0 | |
| 06/08 13:31 | 01174952218886 | | 2668 | TRANSMIT G3 | 6 | NG 04'30 |
| | | | | | 6 | |
| 06/08 13:38 | 01174952218886 | | 2669 | TRANSMIT ECM | 43 | OK 10'03 |
| 06/08 19:59 | 0118227537315 | | 2670 | TRANSMIT ECM | 11 | OK 05'46 |
| 06/09 10:03 | 15712738300 | | 2671 | TRANSMIT ECM | 2 | NG 00'28 |
| | | | | | 2 | STOP |
| 06/09 10:05 | 15712738300 | | 2672 | TRANSMIT ECM | 10 | OK 02'15 |
| 06/09 16:49 | 15712732885 | | 2674 | TRANSMIT ECM | 2 | OK 00'48 |
| 06/12 11:06 | 13017628663 | | 2675 | TRANSMIT ECM | 1 | OK 00'19 |